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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/765,108	03/27/1997	MONTY KRIEGER	MIT6620CIP	5650

7590 03/05/2002

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/765,108

Applicant(s)

Krieger et al.

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on BPAI remand of 09/25/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15, 19-22, and 44-50 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15, 19-22, and 44-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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I) Claims 11 to 15, 19 to 22 and 44 to 50 are pending in the instant application.

II) The instant application has been remanded to the examiner of record by the Board of Patent Appeals and Interferences for clarification of the outstanding issues, to afford Applicant an opportunity to respond to any rejections of record which might have been overlooked in the Appeal Brief and to apply a new reference based upon Applicant's admission during the oral hearing that was conducted on 16 August of 2001 that CD36 binds to LDL and acetylated LDL. The Board also indicated that Applicant may wish to use this opportunity to distinguish between the issues in the instant application and those principals which were expounded by the court in the decisions of *In re Bell*, 26 USPQ2d 1529, (Fed. Cir. 1993) and *In re Deuel*, 34 USPQ2d 1210, (Fed. Cir. 1995).

III) In view of the oral hearing held on 16 August of 2001, PROSECUTION IS HEREBY REOPENED. A restriction requirement and a new grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (a) file a reply under 37 CFR 1.111, because the finality of the action mailed 19 March of 1998 is withdrawn, or,
- (b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but **no new amendments**, affidavits (37 CFR 1.130, 1.131 or 1.132)

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or other evidence are permitted. See 37 CFR 1.193(b)(2). The appeal brief which was filed on 18 February of 1999 was defective because it did not address the three rejections listed as 6, 8 and 9 in the summary of rejections below. The supplemental brief must address the new grounds of rejection as well as the grounds of rejection listed as 8 and 9 in the summary of rejections.

IV) In view of the papers filed 23 December of 1996, the inventorship in this nonprovisional application has been changed by the deletion of Alan M. Pearson and Atilio Rigoti.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

V) The Board has expressed concern that Alan M. Pearson is listed as an Applicant on some of the correspondence in the instant application and, in particular, on the declaration under 35 U.S.C. § 1.132 which was submitted on 05 January of 1998. The inclusion of Alan M. Pearson and/or Atilio Rigoti in the list of "Applicants:" in the correspondence filed by Applicant should be of no consequence to the prosecution of the instant application since the inventorship of the **claimed** invention has been expressly identified by Applicant as Monty Krieger and Susan L. Acton in Paper Number 6, filed 23 December, 1996. Because the declaration under 35 U.S.C. § 1.132 was made by "the inventor" of the claimed subject matter to which it has been applied, it is unclear as to why the activities of Alan M. Pearson are of concern.

VI) The information disclosure statement which was filed on 05 May 1998 will not be considered because it is not in compliance with 37 C.F.R. § 1.97(d). Specifically, it was filed after

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a Final Rejection but was not accompanied by a certification as specified in 37 C.F.R. § 1.97(e), a petition and a petition fee. Further, it did not contain copies of the documents cited therein (37 C.F.R. § 1.98(d)(1) and it did not specifically identify that prior U.S. Patent Application from which priority is claimed and in which a copy of each of the cited document can be found.

VII) It is noted that either of claims 14 or 15 would be allowable if written in independent form without reference to those elements in the claims from which they depend, upon which rejections under 35 U.S.C. 112, second paragraph, have been based. For example, a claim to "an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO:4, 6 or 8" would be allowable.

VIII) The following is a summary of the outstanding grounds of rejection.

1) Claims 11 to 13, 19 to 22 and 44 to 50 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the production of an isolated nucleic acid encoding a scavenger receptor protein lacking one of the amino acid sequences that are disclosed in SEQ ID NOs:4, 6 and 8 of the instant application for those reasons of record as applied to claims 9 to 13, 15, 17, 19 to 22 and 44 to 50 in section 5 of Paper Number 10.

2) Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not provide an adequate written description of a nucleic acid which encodes a human scavenger receptor protein such that an

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artisan could make and use that nucleic acid, for those reasons of record in section 4 of Paper Number 10.

3) Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record in section 6 of Paper Number 10. This claim has been rejected because it is drawn to a method without steps. This claim requires the inhibition of a process but does not require the administration of any agent to achieve the required inhibitory effect and the instant specification does not provide the guidance needed to practice the claimed method without resort to substantial undue experimentation.

4) Claims 44 to 50 are rejected under 35 U.S.C. § 112, first paragraph, because they are incomplete for those reasons of record in section 7 of Paper 10. Each of these claims is drawn to a method and yet none of them recite sufficient elements to provide the claimed method.

5) Claims 11 to 15, 19 to 22 and 44 to 50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are indefinite in so far as they recite the term "scavenger receptor protein type BI" as a limitation for those reasons of record in section 8.1 of Paper Number 10.

6) Claims 11, 12, 15, 19 to 22, and 44 to 50 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which applicant regards as the invention. These claims were vague and indefinite because the term “hybridizing” is a conditional limitation and no conditions are recited in these claims. This rejection is **withdrawn** in view of current patent practice. At the time that this rejection was made it was consistent with the patent practice in this art. However, current practice dictates that the recitation of nucleic acid hybridization in a claim in the absence of any hybridization conditions is to be treated as non-limiting because any nucleic acid will “hybridize” to any other nucleic acid under some conditions. Therefore, a claim which recites such a limitation is reasonably interpreted as encompassing any nucleic acid which meets all of the other limitations of the claim since that nucleic acid would meet the “hybridize” limitation solely by virtue of being a nucleic acid.

7) Claim 14 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in section 8.4 of Paper Number 10.

8) Claim 21 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in section 8.5 of Paper Number 10.

9) Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in section 8.6 of Paper Number 10.

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10) Claim 46 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in section 8.7 of Paper Number 10.

11) Claims 11, 19 and 20 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by the Calvo et al. publication (J. Biol. Chem. 268(25):18929-18935, 05 Sept. 1993) for those reasons of record in section 9 of Paper Number 10.

12) Claims 21 and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over the Calvo et al. publication (J. Biol. Chem. 268(25):18929-18935, 05 Sept. 1993) for those reasons of record in section 10 of Paper Number 10.

IX) The following is a new grounds of rejection:

13) Claims 11 and 19 to 22 are rejected under 35 U.S.C. 102(b) as being anticipated by the Oquendo et al. publication (Cell 58:95-101, 14 July 1989). These claims encompass an isolated nucleic acid molecule which encodes a "scavenger receptor protein type BI" and which "hybridizes" to SEQ ID NOs: 3 and 7. As indicated in section 6 above, because the "hybridizes" limitation in these claims is unconditional, they encompass any isolated nucleic acid molecule which encodes a "scavenger receptor protein type BI". The text in the paragraph bridging pages 38 and 39 of the instant specification defines the term "scavenger receptor protein type BI" solely by function. Because Applicant conceded, during the oral hearing which was held on 16 August 2001, that CD36 meets the functional limitations of these claims then the instant claims

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encompass the isolated nucleic acid molecule which was described in Figure 4 of the Oquendo et al. publication more than a year before the filing of the instant application.

X) If Applicant chooses to reply to this action under 37 CFR 1.111, restriction to one of the following inventions is required under 35 U.S.C. 121 for further prosecution on the merits:

- I. Claims 11 to 15 and 19 to 22, drawn to an isolated nucleic acid molecule encoding a “scavenger receptor protein type BI” and a host cell containing that molecule, classified in class 435, subclass 252.3 and class 536, subclass 23.5.
- II. Claims 44 to 47, drawn to a binding assay, classified in class 435, subclass 7.2 and class 436, subclass 501.
- III. Claim 48, drawn to a method of treatment by administering a “scavenger receptor protein type BI”, classified in class 514, subclass 2.
- IV. Claim 49, drawn to a method of treatment of undefined nature, classification undeterminable.
- V. Claim 50, drawn to a diagnostic assay, classified in class 436, subclass 536.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be employed as a probe to study the

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expression of the corresponding gene, which is a process that is unrelated to the binding assay that is invention II. Further, the assay of invention II, as claimed, can be practiced with a purified protein or with a cell which naturally expresses that protein, both of which are products that are materially different from the isolated nucleic acid molecule of invention I.

Inventions III, IV and V are unrelated to one another or to inventions I and II. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case inventions II to V are four different methods which achieve different objectives by employing different reagents and different steps, each having a different mode of operation. Further, the methods that are inventions III to V do not employ or produce the isolated nucleic acid molecule that is invention I.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and because the examination of these multiple inventions in a single application has proven to be an undue burden, restriction for further examination purposes as indicated is proper.

Applicant is advised that a reply under 37 CFR 1.111 to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800